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USSN 10/010,160  
3153.00297/PC11854A

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

re patent application of: Rosey, et al.

Serial No: 10/010,160

Filed: November 9, 2001

For: NOVEL THERAPEUTIC COMPOSITIONS FOR TREATING INFECTION BY  
LAWSONIA SPP.

Attorney Docket No: 3153.00297

#12  
Jm  
9/16/03

**RESPONSE TO RESTRICTION REQUIREMENT**

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Mail Stop Non-Fee Amendments  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This response is being submitted in response to an Office Action dated July 1, 2003, Paper No. 11. Applicants hereby petition for an extension of time to respond to the outstanding Office Action for one (1) month. Enclosed herewith is a check in the amount of \$110.00 in payment therefor.

Restriction to one of the following Groups was required under 35 U.S.C. § 121:

I. Claims 1-16 and 17-21 drawn to Lawsonia intracellularis recombinant protein and a vaccine composition classified in class 530, subclass 350.

II. Claims 22-24, 30-33, 37-50 drawn to Lawsonia intracellularis vaccine vector, DNA, vector and a host cell classified in class 536, subclass 23.7.

III. Claims 25-26 drawn to an antibody classified in class 424, subclass 130.1.

IV. Claims 27-28 drawn to a method of diagnosing Lawsonia intracellularis infection using antibody classified in class 435, subclass 7.22.

V. Claim 29 drawn to a method of diagnosing Lawsonia intracellularis past infection using protein classified in class 435, subclass 7.

VI. Claims 34-36 drawn to a method of detecting Lawsonia intracellularis using DNA, classified in class 435, subclass 69.1.

Applicants provisionally elect Group II, claims 22-24, 30-33, and 37-50 for prosecution purposes, with traverse. Additionally, Applicants elect SEQ ID No. 1 corresponding to plasmid pGTE#2 flhB (Accession Number NM00/16477). Applicants hereby conditionally withdraw claims 1-21, 25-29, and 34-36 from prosecution, without prejudice, and request reconsideration of the restriction requirement.

Applicants traverse the restriction requirement based on the following grounds. It is respectfully submitted that the restriction requirement practice was established to promote efficiency of prosecution in the United States Patent Office. All the groups of claims generally relate to novel therapeutic compositions for the treatment and/or prophylaxis of intestinal disease conditions caused or exacerbated by lawsonia intracellularis or similar organism. All of the groups of claims relate to a gene directed from lawsonia intracellularis, which encodes an immunogenic polypeptide. Furthermore, all of the groups of the claims relate to the gene and polypeptide encoded by the gene, and various uses thereof. It is well accepted practice in the United States Patent Office to claim a recombinant protein of vaccine composition relating to the protein, vaccine vector, DNA, host cells thereof, antibodies relating to the protein, and methods of treatment utilizing the protein in the same application and without restriction. Accordingly, Applicants respectfully submit that it is entirely reasonable, and would not present an undue burden upon the Examiner, for all of the groups of claims to be prosecuted in a single application. It is respectfully submitted that examination of all of these groups of claims in a single application would be efficient, thereby promoting the grounds for the establishment of the restriction requirement practice. Hence, it is respectfully requested that the restriction should not be required and that Applicants have traversed the restriction requirement. However, as stated above, Applicants have provisionally elected the claims of Group II and SEQ ID No. 1, corresponding to plasmid pGTE#2 flhB (Accession Number NM00/16477). Applicants also provisionally withdraw claims 1-21, 25-29, and 34-36, without prejudice, pending reconsideration of the restriction requirement.

The present application is now in condition for allowance, which allowance is respectfully solicited.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,



KOHN & ASSOCIATES, PLLC

A handwritten signature in black ink, appearing to read "Kenneth I. Kohn", written over a horizontal line.

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Date: August 29, 2003

**CERTIFICATE OF MAILING**

Express Mail Mailing Label No.: EL 976 237 236 US  
Date of Deposit: August 29, 2003

I hereby certify that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office To Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop Non-Fee Amendments, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

A handwritten signature in black ink, appearing to read "Marie M. DeWitt", written over a horizontal line.  
Marie M. DeWitt

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